

REMARKS

Claims 95 and 96 have been cancelled. New claims 101 and 102 have been added. Claims 90-94 and 97-102 are pending in the present application.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Objection to Figures

Figures 2A-2E were objected to for failing to comply with 37 CFR 1.84 because of the top margins. New Figures 2A-2E that comply with 37 CFR 1.84 are submitted herein.

II. Objections to Claims 95 and 96

Claims 95 and 96 were objected to under 37 CFR 1.75 as being substantial duplicates of claim 94. The Office Action stated:

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is unclear that the trichodiene synthase of claim 94 from *Fusarium venenatum* strain ATCC 20334 differs from the trichodene synthase encoded by SEQ ID NO: 1 and from the trichodiene synthase contained in pTri5. SEQ ID NO: 1 and pTri5 are both obtained from *Fusarium venenatum* strain ATCC 20334 and therefore should be the same trichodiene synthase of claim 94 from *Fusarium venenatum* strain ATCC 20334.

Claims 95 and 86 have been cancelled and rewritten as independent claims as suggested by the Examiner.

For the foregoing reason, Applicants submit that this objection has been overcome and respectfully request withdrawal of the objection.

III. The Rejection of Claims 94 and 100 under 35 U.S.C. § 112, First Paragraph

Claims 94 and 100 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action stated:

Since the specific *Fusarium venenatum* cells deposited at ATCC 20334 are essential to the claimed invention, they must be obtainable by a repeatable

method set forth in the specification or otherwise readily available to the public. The invention does not recite use of any cells but instead specifically claims *Fusarium venenatum* cells deposited at ATCC as strain ATCC 20334. The *Fusarium venenatum* cells deposited at ATCC as strain ATCC 20334 are commercially available, however, commercial availability is not necessarily evidence that the Public will have access to the material for the life of a Patent (see MPEP 2404.01) (emphasis added). Others deposited the *Fusarium venenatum* of the invention, their availability in an unrestricted form for the life of a patent issued on the instant application cannot be ensured. Applicants must therefore deposit the specific *Fusarium venenatum* recited in the claims and thus satisfy the deposit requirement under 37 CFR 1.801-1.809 (see enclosed Suggestion for deposit of biological material).

This rejection is respectfully traversed.

CPR 1.802(b) states that public access during the term of the patent may affect the enforceability of the patent, and that in order to ensure that the cells are available for the life of the patent, the applicant must satisfy the deposit requirement under 37 CFR 801-1.809. However, 37 C.F.R. 1.802(b) further states that "[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public ..."

Applicants enclose a copy of page 178 of the ATCC catalogue for 1991 which lists *Fusarium* ATCC 20334. Also attached are pages from ATCC's website (www.atc.org) that disclose the strain is commercially available and may be purchased (submitted in the Amendment of September 28, 2001). Clearly, these publications establish that this strain was known prior to Applicants' filing date.

Applicants in the Amendment of September 28, 2001, pointed out that when the Patent Office adopted the rules on the deposit of biological materials, it issued comments on interpreting and applying the rules. See 54 FR 34880. The comments regarding the terms "known and readily available" in 37 C.F.R. 1.802(b) are set forth at page 23 of 54 FR 34880 as follows:

Even where access to biological material is required to satisfy these statutory requirements, a deposit may not be necessary if access sufficient to satisfy these requirements is otherwise available.

For example, applicant could show that the biological material is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient....

By showing that a biological material is known and readily available or by making a deposit in accordance with these rules,

applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of the deposited material during and after the period of enforceability of the patent, the examiner need not be unduly concerned about continued access to the public. Unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969) (emphasis added).

The above-noted comments on interpreting and applying the deposit rules clearly provide that although there is a public interest in the availability of the deposited material during and after the period of enforceability of the patent, the examiner need not be unduly concerned about continued access to the public, unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement. The Office Action states: "The *Fusarium venenatum* cells deposited at ATCC under ATCC 20334 are commercially available, however, commercial availability is not necessarily evidence that the public will have access to the material for the life of a patent (see MPEP 2404.01) (emphasis added)." However, the Office Action fails to note that MPEP 2404.01 further states: "The Office will accept commercial availability as evidence that a biological material is known and readily available only when evidence is clear and convincing that the public has access to the material." The MPEP follows the comments on interpreting and applying the rules under 54 FR 34880.

Applicants enclose a letter from Elizabeth Kerrigan of the American Type Culture Collection dated July 10, 2003, which confirms that *Fusarium* ATCC 20334 is preserved in the open collection of the ATCC and is "known and readily available". The Kerrigan letter provides clear and convincing evidence that the public has access to the material.

Applicants submit that the microorganism recited in the claims is "known and readily available" and, therefore, Applicants do not have to provide the assurances requested in the Office Action.

For the foregoing reason, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

IV. The Rejection of Claims 97-100 under 35 U.S.C. § 112, First Paragraph

Claims 97-100 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action states:

The invention recites isolated functional fragments of trichodiene synthase. In view of the unpredictability of the art of predicting the functional nature of fragments of SEQ ID NO 2 deleted of any number of amino acids from the C-terminus and/or the N-terminus, undue experimentation would be required to practice the claimed methods with reasonable expectation of success, absent a specific and detailed description in the specification. Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/functional characteristics of a protein from primary amino acid sequence alone, the lack of working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

This rejection is respectfully traversed.

A fragment having trichodiene synthase activity is defined on page 22, lines 8-11, of Applicants' specification: "A fragment of SEQ ID NO. 2 is a polypeptide having one or more amino acids deleted from the amino and/or carboxyl terminus of this amino acid sequence. Preferably, a fragment contains at least 290 amino acid residues, more preferably at least 320 amino acid residues, and most preferably at least 350 amino acid residues." The fragments having trichodiene synthase activity, claimed in the instant invention, involve simply removing one or more amino acids from the amino and/or carboxyl terminus of SEQ ID NO: 2. It is well within the skill in the art to remove one or more amino acids from the amino and/or carboxyl terminus of SEQ ID NO: 2 by genetic manipulation of the gene and then assay the encoded protein fragment for trichodiene synthase activity as demonstrated in Example 10 of the specification. One of ordinary skill in the art would not find this to be undue experimentation.

In the Amendment of May 7, 2003 Applicants submitted that claims to such fragments, as claimed herein, are allowable subject matter as is evidenced by U.S. Patent Nos. 6,221,644, 6,372,464, and 6,489,154, which have similar disclosures as the instant case. However, the Office Action provided no explanation for the difference in examination of the instant application relative to U.S. Patent Nos. 6,221,644, 6,372,464, and 6,489,154, even though they have similar disclosures as the instant case, except to state that "each application is reviewed on its own merits."

Claims limited to the amino acid sequence of SEQ ID NO. 2 would not adequately protect the inventors. One of ordinary skill in the art could make a fragment of SEQ ID NO. 2 by

simply removing one or more amino acids from the amino and/or carboxyl terminus of the polypeptide while retaining the trichodiene synthase activity thereby circumventing the literal scope of Applicants' patent rights.

For the foregoing reasons, Applicants submit that the claims overcome the rejections under 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejections.

V. The Rejection of Claims 97-100 under 35 U.S.C. § 112, First Paragraph

Claims 97-100 were rejected under 35 U.S.C. 112, first paragraph, because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record in the Office Action filed October 21, 2002, and is restated below.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants teach full-length trichodiene synthase from *Fusarium venenatum*. Applicants do not teach any fragments of trichodiene synthase or what domains or regions are required for functional trichodiene synthase. Therefore, there is no disclosure of a structure-function relationship between the sequence of SEQ ID NO 2 and trichodiene synthase activity. Given the large size and diversity of fragments generated by deletion at the N and/or C-terminus and the inability to determine which will also have the essential element, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

This rejection is respectfully traversed.

Applicants submit that the arguments presented in Section V above are sufficient to overcome the instant rejections.

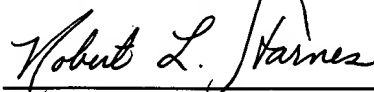
For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejections.

VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Date: March 3, 2004

Respectfully submitted,

A handwritten signature in cursive script, reading "Robert L. Starnes". The signature is written in dark ink and is positioned above a horizontal line.

Robert L. Starnes, Ph.D.
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ATCC publishes a separate catalogue of yeast strains.

STRAIN DESCRIPTIONS

Fusarium equiseti (continued)

- †44413 L Hornok 22-107. Alfalfa root, Hungary. Taxonomy (Trans. Br. Mycol. Soc. 74: 73-78, 1980). (Medium 338 24C) Shipped: Test tube.
- †46469 G. Morgan-Jones. *Heterodera glycines* cysts, soybean field, Missouri. Isolation (Nematropica 11: 155-163, 1981). (Medium 338 24C) Shipped: Freeze-dried.
- †56090 A. Bottalico ITM-192. Durum wheat stem, Italy. (Medium 338 25C under light 12 hrs on/12 hrs off) Shipped: Freeze-dried.
- †60276 M. Baxter MU 1006 — H.M. Hussein. Maize husk, New Zealand. (Medium 338 26C under black light) Shipped: Test tube.
- †60316 G.A. Neish 80.023 — G. Platford. [DAOM 180360] Strawberry field soil, Canada. (Medium 338 26C under black light) Shipped: Test tube.
- †60383 NRRL 5909. (Medium 338 24C) Shipped: Freeze-dried.
- †62721 R.G. Roberts 84-41. Sunflower seed, North Carolina. Isolation (Can. J. Bot. 64: 1964-1971, 1986). (Medium 336 24C) Shipped: Freeze-dried.

Fusarium flocciferum Corda

- 24371 CMI 13515 — W. Gams. Wheat field soil, Germany. (Medium 338 24C) Shipped: Freeze-dried.

Fusarium fusarioides (Fragoso et Ciferri) Booth: See also *Dactylium fusarioides*, teleomorph

- 24372 CMI 128101 — S.I. Ahmend. [CBS 124.73] Soil, Pakistan. (Medium 338 24C) Shipped: Freeze-dried.
- 62725 R.G. Roberts 84-154. Sunflower seed, Georgia. Isolation (Can. J. Bot. 64: 1964-1971, 1986). (Medium 336 24C) Shipped: Freeze-dried.

Fusarium graminearum Schwabe: See also *Gibberella zeae*, teleomorph

- †15624 W.L. Gordon 2611-SA 1153. Corn stalk, Canada. (Medium 336 26C) Shipped: Freeze-dried.
- †20329 RHM Res. Ltd. I 7/3 — G. Scammell. United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 336 30C) Shipped: Test tube.
- †20330 RHM Res. Ltd. I 8/3 — G. Scammell. Derived from parent strain IO after 1100 hrs culture, United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 338 30C) Shipped: Test tube.
- †20331 RHM Res. Ltd. I 9/2 — G. Scammell. Derived from parent strain IO after 1100 hrs culture, United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 338 30C) Shipped: Test tube.
- †20332 RHM Res. Ltd. I 15/2 — G. Scammell. Derived from parent strain IO after 1100 hrs culture, United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 323 30C) Shipped: Test tube.
- †20333 RHM Res. Ltd. I 16/2 — G. Scammell. Derived from parent strain IO after 1100 hrs culture, United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 323 30C) Shipped: Test tube.
- †20334 RHM Res. Ltd. I 0/5 — G. Scammell. [CMI 145425] Soil, United Kingdom. Production of edible protein substances (U.S. Pats. 3,937,654 and 3,937,693). Note: This material is cited in a U.S. and/or other Patent and may not be used to infringe the patent claims. (Medium 323 30C) Shipped: Freeze-dried.
- †24373 CMI 160243 — P. Martin. [CBS 316.73] *Zea mays*, South Africa. (Medium 338 24C) Shipped: Freeze-dried.
- †26557 CMI 155426 — C.J. Mirocha. *Zea mays* moldy grain, USA. Produces zearalenone (F-2 toxin) (J. Stored Prod. Res. 8: 71-75, 1972). (Medium 336 24C) Shipped: Test tube.

- †34909 M. Palyusik F 59. [NRRL 6392] Millet, Hungary. Produces mycotoxins (Appl. Environ. Microbiol. 32: 579-584, 1976). (Medium 338 24C) Shipped: Freeze-dried.
- †34912 M. Palyusik F 184a. [NRRL 6394] Millet, Hungary. Produces mycotoxins (Appl. Environ. Microbiol. 32: 579-584, 1976). (Medium 338 24C) Shipped: Freeze-dried.
- †36882 E.L. Hintikka 72192 — H. Heiskanen. Barley, Finland. (Medium 335 26C) Shipped: Test tube.
- †36884 E.L. Hintikka 72299 — H. Heiskanen. Barley, Finland. (Medium 335 26C) Shipped: Freeze-dried.
- †36885 E.L. Hintikka 72322 — H. Heiskanen. Wheat, Finland. (Medium 335 26C) Shipped: Freeze-dried.
- †44418 L. Hornok 22-39. Winter wheat seed, Hungary. Taxonomy (Trans. Br. Mycol. Soc. 74: 73-78, 1980). (Medium 338 24C) Shipped: Test tube.
- †46779 NRRL 5883. Corn. Produces vomitoxin (Appl. Environ. Microbiol. 43: 967-970, 1982). (Medium 336 24C) Shipped: Freeze-dried.
- †56091 A. Bottalico ITM-124. Rice stem, Italy. (Medium 338 25C under light 12 hrs on/12 hrs off) Shipped: Freeze-dried.
- †56092 A. Bottalico ITM-126. Soft wheat stem, Italy. (Medium 338 25C under light 12 hrs on/12 hrs off) Shipped: Freeze-dried.
- †56093 A. Bottalico ITM-127. Maize ear, Italy. (Medium 338 25C) Shipped: Freeze-dried.
- †56748 NRRL 5864. Produces zearalenone. (Medium 336 24C) Shipped: Freeze-dried.
- †56749 NRRL 6012. Produces moniliformin. (Medium 336 24C) Shipped: Freeze-dried.
- †58667 K. Kallela 7137-18 — H. Heiskanen. Fodder, Finland. Produces zearalenone (Nord. Veterinaarmed. 33: 454-460, 1981). (Medium 307 26C under light 12 hrs on/12 hrs off) Shipped: Test tube.
- †60289 M. Baxter MU 1011 — H.M. Hussein. Maize grain, New Zealand. (Medium 338 26C under black light) Shipped: Test tube.
- †60309 G.A. Neish GAN 905-7-A. [DAOM 177410] White winter wheat, Canada. Produces vomitoxin (Can. J. Plant Sci. 61: 811-815, 1981) and zearalenone (*ibid.*; Can. J. Plant Pathol. 4: 191-194, 1982). (Medium 338 26C under black light) Shipped: Freeze-dried.
- †60643 J. Chelkowski KF 208. (Medium 336 26C) Shipped: Test tube.
- †60880 M. Baxter MU 1027 — H. Hussein. Maize grain, New Zealand. (Medium 338 24C under black light) Shipped: Test tube.
- †60881 M. Baxter MU 1028 — H. Hussein. Maize grain, New Zealand. (Medium 338 24C under black light) Shipped: Test tube.

Fusarium heterosporum Nees

- †15625 W.L. Gordon 3396. Raspberry, Scotland. Heterothallic. Mating type A. (Medium 336 26C) Shipped: Test tube.
- †15626 W.L. Gordon 2883-SA 37. Heterothallic. Mating type a. (Medium 336 26C) Shipped: Test tube.
- †15627 W.L. Gordon 2883 — P. Salisbury. Canker on white pine, Canada. Heterothallic. Mating type a. (Medium 336 26C) Shipped: Freeze-dried.
- †15628 W.L. Gordon 2857-SA 89. Heterothallic. Mating type A. (Medium 336 26C) Shipped: Freeze-dried.
- †15629 W.L. Gordon 2798 — J. Sibalis. Cankered rose twig, Canada. Heterothallic. Mating type A. (Medium 336 26C) Shipped: Test tube.
- †32872 B.M. Cunfer F73-1. Ergot honeydew, Georgia. Sphacelial stage of *Claviceps purpurea* and *C. paspali*. Possible biological control, capable of preventing sclerotial formation (Phytopathology 65: 1372-1374, 1975; *ibid.*, 66: 449-452, 1976). (Medium 336 15-25C) Shipped: Freeze-dried.
- †44419 L. Hornok 22-115. Winter wheat leaf, Hungary. Taxonomy (Trans. Br. Mycol. Soc. 74: 73-78, 1980). (Medium 338 24C) Shipped: Test tube.
- †48715 A.S. Foudin. *Festuca arundinacea*, Montana. Head-scab (Plant Dis. 66: 866, 1982). (Medium 338 28C under light) Shipped: Freeze-dried.
- †52540 W.F.O. Marasas MRC 1816. [Gerlach 62229] (Medium 338 24C) Shipped: Freeze-dried.



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July 10, 2003

Dr. Wendy T. Yoder
Novozymes Biotech Inc.
1445 Drew Ave.
Davis, Calif. 95616 USA

Dear Dr. Yoder,

This letter is to inform you that *Fusarium venenatum* Nirenberg deposited as *Fusarium graminearum* Schwabe, anamorph strain, ATCC# 20334, is currently publicly available for purchase from our Mycology Collection. I have attached a link to the product page from our web-site:
<http://www.atcc.org/SearchCatalogs/longview.cfm?view=fy,3273597,20334&text=20334&max=20>

It was made available as a catalog item on February 3, 1976. It was first published in our 1978 catalog, page 274. Please contact me if you have any further questions. Thank you.

Best Regards,

A handwritten signature in cursive script that reads "Elizabeth Kerrigan".

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Fungi, Yeasts, & Yeast Genetic Stock

ATCC Number	Description	Designation	View
20334	<i>Fusarium venenatum</i> Nirenberg deposited as <i>Fusarium graminearum</i> Schwabe, anamorph	I O/5 [A 3/5; IMI 145425; NRRL 26139]	
9256	<i>Candida utilis</i> (Henneberg) Lodder et Kreger-van Rij, anamorph deposited as <i>Torulopsis utilis</i> var. <i>major</i> Thaysen et Morris, anamorph	NRRL Y-1084 [CBS 841; CCRC 20334; DSM 70167; IFO 0626; JCM 2311; NCYC 359; VKM Y-768; VTT C-79091]	
4020334	<i>Saccharomyces cerevisiae</i> Hansen, teleomorph (budding yeast)	BY4743-YER012W [20334]	

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Designations:	I O/5 [A 3/5; IMI 145425; NRRL 26139]
Depositors:	RHM Res., Ltd.
History:	ATCC<<--RHM Res., Ltd. <<-- G. Scammell
Biosafety Level:	1
Growth Conditions:	ATCC medium: 323 Malt agar medium Temperature: 30.0 C
Permits/Forms: In addition to the MTA mentioned above, other ATCC and/or regulatory permits may be required for the transfer of this ATCC material. Anyone purchasing ATCC material is ultimately responsible for obtaining the permits. Please click here for information regarding the specific requirements for shipment to your location.	
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Applications:	produces edible mycoprotein produces alkaline protease [16197] produces single-cell protein [SCP] transformation host [17043]
Subcollection:	Fungi
References:	2956: Solomons GL , Scammell GW . Production of edible protein substances. US Patent 3,937,654 dated Feb 10 1976 2957: Towersey PJ , et al.. Production of edible protein containing substances. US Patent 3,937,693 dated Feb 10 1976 16197: Milchwissenschaft 47: 147-148, 1992. 17043: Royer JC , et al. <i>Fusarium graminearum</i> A 3/5 as a novel host for heterologous protein production. Bio-Technology 13: 1479-1483, 1995. PubMed: 9636307 39091: O'Donnell K , et al. Molecular phylogenetic, morphological, and mycotoxin data support reidentification of the Quorn mycoprotein fungus as <i>Fusarium venenatum</i> . Fungal Genet. Biol. 23: 57-67, 1998. PubMed: 9501477

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